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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,832	07/10/2000	SUZANNE CORY	017227/0159	3471

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/508,832**

Applicant(s)  
**Cory et al**

Examiner  
**Ungar**

Art Unit  
**1642**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 15, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-44 and 51-61 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-44 and 51-61 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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1. Claims 1-44 and 51-61 are pending in the application and are currently under prosecution.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13:

Group I, claims 1-5, 21-28 and 61 are drawn to a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having one or more of the identifying characteristics of Bim or a derivative or homologue thereof, wherein the nucleic acid encodes SEQ ID NO:2, is SEQ ID NO:1

Group II, claims 1-5, 21-28 and 61 are drawn to a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having one or more of the identifying characteristics of Bim or a derivative or homologue thereof, wherein the nucleic acid encodes SEQ ID NO:4, is SEQ ID NO:3.

Group III, claims 1-5, 21-28 and 61 are drawn to a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having one or more of the

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identifying characteristics of Bim or a derivative or homologue thereof, wherein the nucleic acid encodes SEQ ID NO:6, is SEQ ID NO:5.

Group IV, claims 1, 6-9, 21-28 and 61 are drawn to a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having one or more of the identifying characteristics of Bim or a derivative or homologue thereof, wherein the nucleic acid encodes SEQ ID NO:8, is SEQ ID NO:7.

Group V, claims 1, 6-9, 21-28 and 61 are drawn to a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having one or more of the identifying characteristics of Bim or a derivative or homologue thereof, wherein the nucleic acid encodes SEQ ID NO:10, is SEQ ID NO:9.

Group VI, claims 10-14, 29-36, 51 and 60 are drawn to a polypeptide comprising the amino acid sequence of Bim or having one or more identifying characteristics thereof or a derivative or homologue thereof wherein the polypeptide is SEQ ID NO:2, is encoded by SEQ ID NO:1.

Group VII, claims 10-14, 29-36, 51 and 60 are drawn to a polypeptide comprising the amino acid sequence of Bim or having one or more identifying characteristics thereof or a derivative or homologue thereof wherein the polypeptide is SEQ ID NO:4, is encoded by SEQ ID NO:3.

Group VIII, claims 10-14, 29-36, 51 and 60 are drawn to a polypeptide comprising the amino acid sequence of Bim or having one or more identifying characteristics thereof or a derivative or homologue thereof wherein the polypeptide is SEQ ID NO:6, is encoded by SEQ ID NO:5.

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Group IX, claims 10, 15-20, 51 and 60 are drawn to a polypeptide comprising the amino acid sequence of Bim or having one or more identifying characteristics thereof or a derivative or homologue thereof wherein the polypeptide is SEQ ID NO:8, is encoded by SEQ ID NO:7.

Group X, claims 10, 15-20, 51 and 60 are drawn to a polypeptide comprising the amino acid sequence of Bim or having one or more identifying characteristics thereof or a derivative or homologue thereof wherein the polypeptide is SEQ ID NO:10, is encoded by SEQ ID NO:7.

Group XI, claim 37 is drawn to a method of modulating activity of Bim in a mammal to increase Bim activity.

Group XII, claim 37 is drawn to a method of modulating activity of Bim in a mammal to decrease Bim activity.

Group XIII, claim 37 is drawn to a method of modulating activity of Bim in a mammal which neither increases nor decreases Bim activity.

Group XIV, claim 38 is drawn to a method of modulating expression of Bim in a mammal to upregulate Bim expression.

Group XV, claim 38 is drawn to a method of modulating expression of Bim in a mammal to downregulate Bim expression.

Group XVI, claim 38 is drawn to a method of modulating expression of Bim in a mammal to which neither upregulates or downregulates Bim expression.

Group XVII, claims 39 and 42 are drawn to a method of modulating apoptosis in a mammal comprising administering an agent sufficient to modulate expression of a nucleotide sequence encoding BIM.

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Group XVIII, claims 40 and 43 are drawn to a method of modulating apoptosis in a mammal comprising administering an agent sufficient to modulate activity of BIM.

Group XIX, claims 41 and 44 are drawn to a method of modulating apoptosis in a mammal comprising administering an Bim.

Group XX, claims 52-54 are drawn to an immunointeractive molecule with specificity for Bim or a derivative thereof, a monoclonal antibody.

Group XXI, claims 55-58 are drawn to a method of detecting an immunoreactive molecule, an antibody, in a sample.

Group XXII, claim 59 is drawn to a method of detecting Bim.

3. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

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4. The inventions listed as Groups I-XXII do not relate to a single inventive concept because they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XXI appears to be that they all relate to a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having one or more of the identifying characteristics of Bim or a derivative or homologue thereof. It is noted that derivatives are not limited by the specification. The specification states that derivatives include fragments, parts, portions, chemical equivalents, mutants, homologues (p. 23, lines 10-13). Further, identifying characteristics of Bim include, but are not limited to the features disclosed on pages 34-35 and include a non-apoptosis inducing derivative of any of the described polypeptides. It is noted that neither a homologue nor a mutant are defined by the specification. Genbank Sequence Database (Accession Number AAQ70754), National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland, publicly available March 22, 1995, as reported in EP610842, is a nucleic acid molecule that encodes Beta tubulin which is a non-apoptosis inducing polypeptide and is thus a derivative of a polypeptide having one or more of the identifying characteristics of Bim in that it encodes a polypeptide that comprises numerous fragments of SEQ ID NO:2 (see attached database search results us-09-508-832-2.rng, pages 7-8. .Therefore the technical feature linking the inventions of Groups I-XXII does not constitute a special technical feature as it does not define a contribution over the prior art.

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In view of the above, Group I is considered the main invention.. After that, all other products and methods have been broken out as separate groups (see 37 CFR 1.475(d)).

Group I forms a single general inventive concept. All of the other groups represent different products and methods.

5. Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

6. Group IX and X contain claims directed to more than one species of the generic invention.

Claim 10 is generic to a plurality of disclosed species comprising proteins in different forms with different structures and therefore different functions wherein the forms are (a) homodimeric, claim 19, (b) heterodimeric (claim 20).

7. Groups I-V contain claims directed to more than one species of the generic invention.

Claim 1 is generic to a plurality of disclosed species comprising variant nucleic acid molecules wherein the variants encode polypeptides with different structures and functions, wherein the polypeptide(a) cannot bind with dynein light chain, claim 21, (b) binds dynein light chain, claim 22. Claim 23 will be examined as it is drawn to the elected group.

8. Groups I-V contain claims directed to more than one species of the generic invention.

Claim 1 is generic to a plurality of disclosed species comprising mutated nucleic acid molecules which encode mutated polypeptides wherein the mutations

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lead to different structures and therefore different functions wherein the mutations are those recited in (a) claim 23, (b) claim 24, © claim 25, (d) claim 26, (e) claim 27. Applicant must identify those mutants that read on the species above draw to dynein light chain binding. Applicant must elect a single mutant drawn to the elected group above. If none of the mutants read on either of the species above, Applicant must elect a single mutant from this group combined with the group above.

9. Groups V-VIII contain claims directed to more than one species of the generic invention.

Claim 10 is generic to a plurality of disclosed species comprising variant nucleic acid molecules wherein the variants encode polypeptides with different structures and functions, wherein the polypeptide(a) cannot bind with dynein light chain, claim 29, (b) binds dynein light chain, claim 30. Claim 31 will be examined as it is drawn to the elected group.

10. Groups V-VIII contain claims directed to more than one species of the generic invention.

Claim 10 is generic to a plurality of disclosed species comprising mutated nucleic acid molecules which encode mutated polypeptides wherein the mutations lead to different structures and therefore different functions wherein the mutations are those recited in (a) claim 32, (b) claim 33, © claim 34, (d) claim 35, (e) claim 36. Applicant must identify those mutants that read on the species above draw to dynein light chain binding. Applicant must elect a single mutant drawn to the elected group above. If none of the mutants read on either of the species above,

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Applicant must elect a single mutant from this group combined with the group above.

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R.

§ 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

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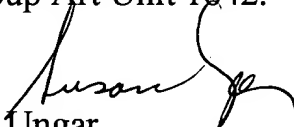
14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, Ph.D. whose telephone number is (703) 308-305-2181.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, PhD who may be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

  
Susan Ungar  
Primary Patent Examiner  
December 14, 2001